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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,963	12/30/1999	ROGER L. BUIS	BO999023-003	7122

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EXAMINER

LUDWIG, MATTHEW J

ART UNIT	PAPER NUMBER
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2178

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10/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/475,963	Applicant(s) BUIS ET AL.	
	Examiner MATTHEW J. LUDWIG	Art Unit 2178	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16, 24-, 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16, 24-, 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the Amendment received 8/4/08.
2. Claims 10-16, 24, and 26-31, are pending in the case. Claims 10 and 24 are independent claims.
3. Claims 10-16, 24, and 26-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Umen et al., USPN 6,854,086 filed (11/13/02) in view of Shoup USPN 7,076,502 filed (7,076,502).

Claim Objections

4. Independent claim 10 and 24 are objected because the claim includes language which is ambiguous. More specifically, the limitation which states 'associating a second layout identifier with a second format region defining a second on the document page' is missing what the Examiner believes is the word 'area' prior to the word 'on'. Also, a second ambiguous limitation within independent claim 10 recites 'corresponding to the second layout identifier to each data record associated with second first layout identifier'. It is unclear whether the word 'second' or 'first' should appear within the limitation but the examiner believes one should be eliminated to clarify the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 10-16, 24, and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umen et al., USPN 6,854,086 filed (11/13/02) in view of Shoup et al., USPN 7,076,502 filed (4/12/2004).**

In reference to independent claim 10, Umen teaches:

Section headings may be included in the document templates for identifying the various sections of each document. At each location within the document template where a data object is to be retrieved from the clinical study data base, there is a control code identifying which object is to be retrieved (compare to “*receiving a data stream in which each data record therein is associated with a layout identifier indicating a type of data included within a data record at a first computer*”). See column 17, lines 20-35. Figure 7 and columns 17 & 18 disclose language related to associations made between 'detail' and 'text' which are associated with specific regions of the document and associated with specific content/text objects from a record.

Each of the document templates specifies the type and order of data objects that are to be retrieved from the clinical study database in order to produce a standard drug document in accordance with FDA, EU, Company, or other predetermined document formats. Table 1 lists representative study details that may be specified within representative standard types of documents (compare to “*associating a first layout identifier with a first format region, defining a first area on a document page and associating a second layout identifier with a second format region defining a second on the document page*”). See column 10, lines 35-55. Figure 7 and columns 17 & 18 disclose language related to associations made between 'detail'

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and 'text' which are associated with specific regions of the document and associated with specific content from a record.

When the user selects Document Generation from the main menu, the DMUI provides a series of study selection menus which allow the user to specify whether the desired document pertains to a single study or whether the desired document integrates data from more than one study, and to select the study of interest (compare to “*receiving layout parameters including formatting instructions relating to the presentation of data records in a document and specifying fixed data to be included in a format region each time a particular layout identifier is encountered*”). See column 17, lines 33-67. In addition to specifying study details, text objects, and the arrangement thereof, the document templates may include standard pain text items that are usually included in the respective documents.

The newly formed limitation which states '*fixed data to be included in a format region Each time a particular layout identifier is encountered*' is taught by the reference to Umen. Each of the document templates specifies the type and order of data objects that are to be retrieved from the clinical study database in order to produce a standard drug document in accordance with FDA, EU, Company, or other predetermined document formats. See column 17, lines 33-67 and column 19, lines 25-45.

The Umen reference discloses templates used for specifying the arrangement of information within a particular type of document to be generated. The generated drug data is presented to a user in a specific format based upon a reviewer of the data. A developer may also wish to produce internal company reports, which may also present the same drug data in another customized format. Umen fails to explicitly state layout identifiers controlling placement of each

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data within each format region. However, Shoup teaches a record management system for generating a multi-dimensional view for different measures. A set of records is retrieved in response to a set of queries. More specifically, a layout engine designates specific data into specific regions of the document based upon formatting parameters. See column 16, lines 30-67 and column 17, lines 45-67. Once the formatting information is gathered, the record management system proceeds with the generation of a layout mapping. The layout engine builds the layout mapping in the layout mapping storage unit by utilizing the retrieved formatting information and the record structure foundation formed by the query map and master table index. It would have been obvious to one of ordinary skill in the art, having the teachings of Umen and Shoup before him at the time the invention was made, to modify the data formatting methods of Umen and added the layout engine of Shoup, because it would have given the user an added multi-dimensional view of information based upon formatting instructions.

In reference to dependent claim 11, Umen teaches:

When the DMUI has completed generating the document, the user can provide the document to the word processor for any desired editing or refinement. Additionally, the user may then instruct the word processor to operate the printer for printing the generated document. See column 19, lines 35-45.

In reference to dependent claim 12 and 13, Umen teaches:

The Umen reference discloses templates used for specifying the arrangement of information within a particular type of document to be generated. The generated drug data is presented to a user in a specific format based upon a reviewer of the data. A developer may also wish to produce internal company reports which may also present the same drug data in another

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customized format. Umen fails to explicitly state layout identifiers controlling placement of each data within each format region. However, Shoup teaches a record management system for generating a multi-dimensional view for different measures. A set of records is retrieved in response to a set of queries. More specifically, a layout engine designates specific data into specific regions of the document based upon formatting parameters. Once the formatting information is gathered, the record management system proceeds with the generation of a layout mapping. The layout engine builds the layout mapping in the layout mapping storage unit by utilizing the retrieved formatting information and the record structure foundation formed by the query map and master table index. It would have been obvious to one of ordinary skill in the art, having the teachings of Umen and Shoup before him at the time the invention was made, to modify the data formatting methods of Umen and added the layout engine of Shoup, because it would have given the user an added multi-dimensional view of information based upon formatting instructions.

In reference to dependent claim 14-16, Umen teaches:

The document generation option of the main menu provides access to procedures for generating drug documents on the basis of pre-defined document templates and information contained within the clinical study database. Each of the document templates specifies the type and order of data objects that are to be retrieved from the clinical study database in order to produce a standard drug document. The reference fails to explicitly state each data record formatted within a format region of a first type repeated at the beginning of each page of the document. However, Shoup teaches a record management system for generating a multi-dimensional view for different measures. A set of records is retrieved in response to a set of

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queries. More specifically, a layout engine designates specific data into specific regions of the document based upon formatting parameters. Once the formatting information is gathered, the record management system proceeds with the generation of a layout mapping. The layout engine builds the layout mapping in the layout mapping storage unit by utilizing the retrieved formatting information and the record structure foundation formed by the query map and master table index. It would have been obvious to one of ordinary skill in the art, having the teachings of Umen and Shoup before him at the time the invention was made, to modify the data formatting methods of Umen and added the layout engine of Shoup, because it would have given the user an added multi-dimensional view of information based upon formatting instructions.

In reference to claims 24, and 26-31, the claims reflect the computer program instructions used for performing the methods as claimed in 10-16. In further view of the following, the claims are rejected under similar rationale.

Response to Arguments

7. Applicant's arguments with respect to claims 10-16, 24, and 26-31, have been considered, but are not persuasive.

Applicant amended the independent claims and added language related to the presentation of data records in a document and the placement of data records within first and second format regions. The reference to Umen, and more specifically, column 10, lines 35-55, Figure 7, and columns 17 & 18 disclose language related to associations made between 'detail' and 'text' which are associated with specific regions of the document and associated with specific content from a record. When the user selects Document Generation from the main menu, the

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DMUI provides a series of study selection menus which allow the user to specify whether the desired document pertains to a single study or whether the desired document integrates data from more than one study, and to select the study of interest. In addition to specifying study details, text objects, and the arrangement thereof, the document templates may include standard pain text items that are usually included in the respective documents. The Umen reference discloses templates used for specifying the arrangement of information within a particular type of document to be generated. The generated drug data is presented to a user in a specific format based upon a reviewer of the data. A developer may also wish to produce internal company reports, which may also present the same drug data in another customized format.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Ludwig whose telephone number is 571-272-4127.

The examiner can normally be reached on 9:00am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Hong can be reached on 571-272-4124. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ML

/Stephen S. Hong/

Supervisory Patent Examiner, Art Unit 2178

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